



# Nanotechnology: A Policy Primer

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## Summary

Nanoscale science, engineering and technology—commonly referred to collectively as nanotechnology—is believed by many to offer extraordinary economic and societal benefits. Congress has demonstrated continuing support for nanotechnology and has directed its attention primarily to three topics that may affect the realization of this hoped for potential: federal research and development (R&D) in nanotechnology; U.S. competitiveness; and environmental, health, and safety (EHS) concerns. This report provides an overview of these topics—which are discussed in more detail in other CRS reports—and two others: nanomanufacturing and public understanding of and attitudes toward nanotechnology.

The development of this emerging field has been fostered by significant and sustained public investments in nanotechnology R&D. Nanotechnology R&D is directed toward the understanding and control of matter at dimensions of roughly 1 to 100 nanometers. At this size, the properties of matter can differ in fundamental and potentially useful ways from the properties of individual atoms and molecules and of bulk matter. Since the launch of the National Nanotechnology Initiative (NNI) in 2000 through FY2009, Congress has appropriated approximately \$10.2 billion for nanotechnology R&D. In addition, the President requested an additional \$1.6 billion in funding for nanotechnology R&D for FY2010. While Congress has passed all of the regular appropriations acts, the precise amount provided for FY2010 is currently under evaluation by the agencies and the White House Office of Management and Budget and will likely be published with the President's FY2011 budget request in February 2010. More than 60 nations have established similar programs. In 2006 alone, total global public R&D investments reached an estimated \$6.4 billion, complemented by an estimated private sector investment of \$6.0 billion. Data on economic outputs that are used to assess competitiveness in mature technologies and industries, such as revenues and market share, are not available for assessing nanotechnology. Alternatively, data on inputs (e.g., R&D expenditures) and non-financial outputs (e.g. scientific papers, patents) may provide insight into the current U.S. position and serve as bellwethers of future competitiveness. By these criteria, the United States appears to be the overall global leader in nanotechnology, though some believe the U.S. lead may not be as large as it has been for previous emerging technologies.

Some research has raised concerns about the safety of nanoscale materials. There is general agreement that more information on EHS implications is needed to protect the public and the environment; to assess and manage risks; and to create a regulatory environment that fosters prudent investment in nanotechnology-related innovation. Nanomanufacturing—the bridge between nanoscience and nanotechnology products—may require the development of new technologies, tools, instruments, measurement science, and standards to enable safe, effective, and affordable commercial-scale production of nanotechnology products. Public understanding and attitudes may also affect the environment for R&D, regulation, and market acceptance of products incorporating nanotechnology.

In 2003, Congress enacted the 21<sup>st</sup> Century Nanotechnology Research and Development Act providing a legislative foundation for some of the activities of the NNI, addressing concerns, establishing programs, assigning agency responsibilities, and setting authorization levels. Both the House of Representatives and the Senate remain actively engaged in the NNI. Legislation has been introduced in the House (H.R. 554) and Senate (S. 1482) that would amend the act. The House passed H.R. 554 on February 11, 2009. The Senate has not acted on this legislation. The 111<sup>th</sup> Congress may address policy issues related to the NNI through this or other legislation.

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## Overview

Congress continues to demonstrate interest in and support for nanotechnology due to what many believe is its extraordinary potential for delivering economic growth, high-wage jobs, and other societal benefits to the nation. To date, the Science Committee in the House and Senate Committee on Commerce have directed their attention primarily to three topics that may affect the United States' realization of this hoped for potential: federal research and development (R&D) investments under the National Nanotechnology Initiative (NNI); U.S. international competitiveness; and environmental, health, and safety (EHS) concerns. This report provides a brief overview of these topics—which are discussed in greater detail in CRS reports<sup>1</sup>—and two other subjects of interest to Congress: nanomanufacturing and public attitudes toward, and understanding of, nanotechnology.

Nanotechnology research and development is directed toward the understanding and control of matter at dimensions of roughly 1 to 100 nanometers. At this size, the physical, chemical, and biological properties of materials can differ in fundamental and potentially useful ways from the properties of individual atoms and molecules, on the one hand, or bulk matter, on the other hand.

In 2000, President Clinton launched the NNI to coordinate federal R&D efforts and promote U.S. competitiveness in nanotechnology. Congress first funded the NNI in FY2001 and has provided increased appropriations for nanotechnology R&D in each subsequent year. In 2003, Congress enacted the 21<sup>st</sup> Century Nanotechnology Research and Development Act (P.L. 108-153). The act provided a statutory foundation for the NNI, established programs, assigned agency responsibilities, authorized funding levels, and initiated research to address key issues.

Federal R&D investments are focused on advancing understanding of fundamental nanoscale phenomena and on developing nanomaterials, nanoscale devices and systems, instrumentation, standards, measurement science, and the tools and processes needed for nanomanufacturing. NNI appropriations also fund the construction and operation of major research facilities and the acquisition of instrumentation. Finally, the NNI supports research directed at identifying and managing potential environmental, health, and safety impacts of nanotechnology, as well as its ethical, legal and societal implications.

Most current applications of nanotechnology are evolutionary in nature, offering incremental improvements in existing products and generally modest economic and societal benefits. For example, nanotechnology is being used: in automobile bumpers, cargo beds, and step-assists to reduce weight, increase resistance to dents and scratches, and eliminate rust; in clothes to increase stain- and wrinkle-resistance; and in sporting goods, such as baseball bats and golf clubs, to improve performance.

In the longer term, nanotechnology may deliver revolutionary advances with profound economic and societal implications. Potential applications discussed by the technology's proponents involve various degrees of speculation and varying time-frames. The examples below suggest areas where

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<sup>1</sup> For additional information on these issues, see CRS Report RL34401, *The National Nanotechnology Initiative: Overview, Reauthorization, and Appropriations Issues*, CRS Report RL34493, *Nanotechnology and U.S. Competitiveness: Issues and Options*, and CRS Report RL34614, *Nanotechnology and Environmental, Health, and Safety: Issues for Consideration*, all by John F. Sargent, and CRS Report RL34332, *Engineered Nanoscale Materials and Derivative Products: Regulatory Challenges*, by Linda-Jo Schierow.

such possible revolutionary advances may emerge, and early research and development efforts that may provide insights into how such advances may be achieved.

- **Detection and treatment technologies for cancer and other deadly diseases.** Current nanotechnology disease detection efforts include the development of sensors that can identify biomarkers, such as altered genes, that may provide an early indicator of cancer. One approach uses carbon nanotubes and nanowires to identify the unique molecular signals of cancer biomarkers. Another approach uses nanoscale cantilevers—resembling a row of diving boards—treated with molecules that bind only with cancer biomarkers. When these molecules bind, the additional weight bends the cantilevers indicating the presence and concentration of these biomarkers. Nanotechnology holds promise for showing the presence, location, and/or contours of cancer, cardiovascular disease, or neurological disease. Current R&D efforts employ metallic, magnetic, and polymeric nanoparticles with strong imaging characteristics attached to an antibody or other agent that binds selectively with targeted cells. The imaging results can be used to guide surgical procedures and to monitor the effectiveness of non-surgical therapies in killing the disease or slowing its growth. Nanotechnology may also offer new cancer treatment approaches. For example, nanoshells with a core of silica and an outer metallic shell can be engineered to concentrate at cancer lesion sites. Once at the sites, a harmless energy source (such as near-infrared light) can be used to cause the nanoshells to heat, killing the cancer cells they are attached to. Another treatment approach targets delivery of tiny amounts of a chemotherapy drug to cancer cells. In this approach the drug is encapsulated inside a nanoshell that is engineered to bind with an antigen on the cancer cell. Once bound, the nanoshell dissolves, releasing the chemotherapy drug killing the cancer cell. Such a targeted delivery approach could reduce the amount of chemotherapy drug needed to kill the cancer cells, reducing the side effects of chemotherapy.<sup>2</sup>
- **Clean, inexpensive, renewable power through energy creation, storage, and transmission technologies.** Nanoscale semiconductor catalysts and additives show promise for improving the production of hydrogen from water using sunlight. The optical properties of these nanoscale catalysts allow the process to use a wider spectrum of sunlight. Similarly, nanostructured photovoltaic devices (e.g. solar panels) may improve the efficiency of converting sunlight into electricity by using a wider spectrum of sunlight. Improved hydrogen storage, a key challenge in fuel cell applications, may be achieved by tapping the chemical properties and large surface area of certain nanostructured materials. In addition, carbon nanotube fibers have the potential for reducing energy transmission losses from approximately 7% (using copper wires) to 6% (using carbon nanotube fibers), an equivalent annual energy savings in the United States of 24 million barrels of oil.<sup>3</sup>
- **Universal access to clean water.** Nanotechnology water desalination and filtration systems may offer affordable, scalable, and portable water filtration

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<sup>2</sup> National Cancer Institute website. [http://nano.cancer.gov/resource\\_center/tech\\_backgrounder.asp](http://nano.cancer.gov/resource_center/tech_backgrounder.asp).

<sup>3</sup> *Nanoscience Research for Energy Needs*, Nanoscale Science, Engineering, and Technology Subcommittee, National Science and Technology Council, The White House, December 2004.

systems. Filters employing nanoscale pores work by allowing water molecules to pass through, but prevent larger molecules, such as salt ions and other impurities (e.g. bacteria, viruses, heavy metals, and organic material), from doing so. Some nanoscale filtration systems also employ a matrix of polymers and nanoparticles that serve to attract water molecules to the filter and to repel contaminants.<sup>4</sup>

- **High-density memory devices.** A variety of nanotechnology applications may hold the potential for improving the density of memory storage. For example, IBM has demonstrated the potential to create high-density memory devices (with an estimated storage capacity of 1 terabyte per square inch) by storing information mechanically using thermal-mechanical nanoscale probes to punch nanoscale indentations into a thin plastic film. The probes can be used to read and write data in parallel.<sup>5</sup>
- **Higher crop yield and improved nutrition.** Higher crop yield might be achieved using nanoscale sensors that detect the presence of a virus or disease-infesting particle. Early, location-specific detection may allow for rapid and targeted treatment of affected areas, increasing yield by preventing losses.<sup>6</sup> Nanotechnology also offers the potential for improved nutrition. Some companies are exploring the development of nanocapsules that release nutrients targeted at specific parts of the body at specific times.<sup>7</sup>
- **Self-healing materials.** Nanotechnology may offer approaches that enable materials to “self-heal” by incorporating, for example, nanocontainers of a repair substance (e.g., an epoxy) throughout the material. When a crack or corrosion reaches a nanocontainer, the nanocontainer could be designed to open and release its repair material to fill the gap and seal the crack.<sup>8</sup>
- **Sensors that can warn of minute levels of toxins and pathogens in air, soil or water.** Microfluidic and nanocantilever sensors (discussed earlier) may be engineered to detect specific pathogens (e.g. bacteria, virus) or toxins (e.g., sarin gas, hydrogen cyanide) by detecting their unique molecular signals or through selective binding with an engineered nanoparticle.
- **Environmental remediation of contaminated sites.** The high surface-to-volume ratio, high reactivity, and small size of some nanoscale particles (e.g. nanoscale iron) may offer more effective and less costly solutions to environmental contamination. By injecting engineered nanoparticles into the ground, these characteristics can be employed to enable the particles to move more easily through a contaminated site and bond more readily with targeted contaminants.<sup>9</sup>

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<sup>4</sup> Abraham, M. “Today’s Seawater is Tomorrow’s Drinking Water,” University of California at Los Angeles, November 6, 2006

<sup>5</sup> Vettiger, P. “The ‘millipede’ - nanotechnology entering data storage,” IEEE Transactions on Nanotechnology, March 2002. Vol 1. Issue 1. pp 29-55.

<sup>6</sup> *Nanoscale Science and Engineering for Agriculture and Food Systems*, draft report on the National Planning Workshop, submitted to the Cooperative State Research, Education, and Extension Service of the U.S. Department of Agriculture, July 2003.

<sup>7</sup> Wolfe, Josh. “Safer and Guilt-Free Nano Foods,” Forbes.com, August 10, 2005.

<sup>8</sup> Berger, Michael. “Nanomaterial heal thyself,” Nanowerk Spotlight, June 13, 2007.

<sup>9</sup> EPA website. [http://es.epa.gov/ncer/nano/research/nano\\_remediation.html](http://es.epa.gov/ncer/nano/research/nano_remediation.html).

Nanotechnology is also expected to make substantial contributions to federal missions such as national defense, homeland security, and space exploration and commercialization.

U.S. private sector nanotechnology R&D is now estimated to be twice that of public funding. In general, the private sector's efforts are focused on translating fundamental knowledge and prototypes into commercial products; developing new applications incorporating nanoscale materials; and developing technologies, methods, and systems for commercial-scale manufacturing.

Many other nations and firms around the world are also making substantial investments in nanotechnology to reap its potential benefits. With so much potentially at stake, some members of Congress have expressed interest and concerns about the U.S. competitive position in nanotechnology R&D and success in translating R&D results to commercial products. This has led to an increased focus on potential barriers to commercialization efforts, including the readiness of technologies, systems, and processes for large-scale nanotechnology manufacturing; potential environmental, health, and safety (EHS) effects of nanoscale materials; public understanding and attitudes toward nanotechnology; and other related issues. Both the House of Representatives and the Senate have held hearings in 2008 on amending the 21<sup>st</sup> Century Nanotechnology Research and Development Act. This report provides a macro-level view of federal R&D investments, U.S. competitiveness in nanotechnology, and EHS-related issues.

## The National Nanotechnology Initiative

President Clinton launched the National Nanotechnology Initiative in 2000, establishing a multi-agency program to coordinate and expand federal efforts to advance the state of nanoscale science, engineering, and technology, and to position the United States to lead the world in its development and commercialization. The NNI is comprised of 13 federal agencies that receive appropriations to conduct and fund nanotechnology R&D and 12 other federal agencies with responsibilities for health, safety, and environmental regulation; trade; education; training; intellectual property; international relations; and other areas that might affect nanotechnology. EPA both conducts R&D and has regulatory responsibilities.

Congress has played a central role in the NNI, providing appropriations for the conduct of nanotechnology R&D (discussed below), establishing programs, and creating a legislative foundation for some of the activities of the NNI through enactment of the 21<sup>st</sup> Century Nanotechnology Research and Development Act of 2003. The act authorized appropriations FY2005 through FY2008 for five NNI agencies—the National Science Foundation (NSF), Department of Energy (DOE), National Aeronautics and Space Administration (NASA), Department of Commerce (DOC) National Institute of Standards and Technology (NIST), and Environmental Protection Agency (EPA). Congress remains actively engaged in the NNI. Legislation has been introduced in the House (National Nanotechnology Initiative Amendments Act of 2009, H.R. 554) and Senate (National Nanotechnology Initiative Amendments Act of 2009, S. 1482) that would amend the act. The House passed H.R. 554 on February 11, 2009. The Senate has not acted on this legislation. The 111<sup>th</sup> Congress may address policy issues related to the NNI through this or other legislation.

## Structure

The NNI is coordinated within the White House through the National Science and Technology Council (NSTC) Nanoscale Science, Engineering, and Technology (NSET) subcommittee. The NSET subcommittee is comprised of representatives from 25 federal agencies, White House Office of Science and Technology Policy (OSTP) and Office of Management and Budget.<sup>10</sup> The NSET subcommittee has established several working groups, including the National Environmental and Health Implications (NEHI), National Innovation and Liaison with Industry (NILI), Global Issues in Nanotechnology (GIN), Nanomanufacturing, and Nanotechnology Public Engagement and Communications (NPEC) working groups. The National Nanotechnology Coordination Office (NNCO) provides administrative and technical support to the NSET subcommittee.

## Funding

Funding for the NNI is provided through appropriations to each of the NNI-participating agencies. The NNI has no centralized funding. Overall NNI funding is calculated by aggregating the nanotechnology-related expenditures of each NNI agency. Funding remains concentrated in the original six NNI agencies<sup>11</sup> which accounted for 98.3% of NNI funding in FY2008. The NNI funds fundamental and applied nanotechnology R&D, multidisciplinary centers of excellence, and key research infrastructure. It also supports efforts to address societal implications of nanotechnology, including ethical, legal, EHS, and workforce issues.

For FY2008, Congress appropriated an estimated \$1.491 billion for nanotechnology R&D, more than triple the \$464 million federal investment in 2001. In total, Congress appropriated approximately \$8.4 billion for the NNI since FY2001. President Bush requested \$1.527 billion for nanotechnology R&D in FY2009, a 2.3% increase above the estimated FY2008 funding level. The chronology of NNI funding is detailed in **Table 1**.

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<sup>10</sup> NSET subcommittee members include Bureau of Industry and Security, DOC; Consumer Product Safety Commission; Cooperative State Research, Education, and Extension Service, Department of Agriculture (USDA); Department of Defense (DOD); Department of Education; DOE; Department of Homeland Security; Department of Justice; Department of Labor; Department of State; Department of Transportation; Department of the Treasury; EPA; Food and Drug Administration; Forest Service, USDA; Intelligence Technology Innovation Center; International Trade Commission; NASA; National Institutes of Health (NIH), Department of Health and Human Services (DHHS); National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, (DHHS); NIST, DOC; NSF; Nuclear Regulatory Commission; U.S. Geological Survey, Department of the Interior; and U.S. Patent and Trademark Office, DOC.

<sup>11</sup> The original six agencies were the NSF, DOD, DOE, NIST, NASA, and NIH.

**Table 1. NNI Funding, by Agency**  
 (in millions of current dollars)

Agency	FY 2001 Actual	FY 2002 Actual	FY 2003 Actual	FY 2004 Actual	FY 2005 Actual	FY 2006 Actual	FY 2007 Actual	FY 2008 Actual	FY 2009 Estimate	FY2009 Recovery Act <sup>a</sup>	FY2010 Request
Department of Defense <sup>b</sup>	125	224	220	291	352	424	450	460	464		379
National Science Foundation	150	204	221	256	335	360	389	409	397	108	423
Department of Energy	88	89	134	202	208	231	236	245	337	25	351
National Institutes of Health (DHHS) <sup>c</sup>	40	59	78	106	165	192	215	305	311		326
National Institute of Standards and Technology (DOC)	33	77	64	77	79	78	88	86	87	7	91
National Aeronautics and Space Administration	22	35	36	47	45	50	20	17	17		17
Environmental Protection Agency	5	6	5	5	7	5	8	12	16		18
Other Agencies	1	3	2	5	9	13	19	22	27		35
<b>TOTAL<sup>d</sup></b>	<b>464</b>	<b>697</b>	<b>760</b>	<b>989</b>	<b>1,200</b>	<b>1,351</b>	<b>1,425</b>	<b>1,554</b>	<b>1,657</b>	<b>140</b>	<b>1,640</b>

**Source:** NNI website. <http://www.nano.gov/html/about/funding.html>

- a. Based on preliminary allocations of the American Recovery and Reinvestment Act of 2009 (P.L. 111-5) appropriations. These figures are subject to change. Other NNI agencies with ARRA funding, but not listed in the table, were in the process of determining their allocations at the time this data was published.
- b. According to NSTC, the Department of Defense budgets for FY2006, FY2007, FY2008, and FY2009 include Congressionally directed funding outside the NNI plan. The extent to which such funding is included or not included in reporting of funding in earlier fiscal years is uncertain.
- c. According to NIH, the agency has recently adopted the Research, Condition, and Disease Categorization (RCDC) system to provide more consistent and transparent information to the public about NIH research. The shift to the RCDC process of categorization changes the way individual research projects are assigned to categories. This change will result in some differences in total dollar amounts between the 2008 reports and those issued in previous years. Any difference, whether an increase or decrease in funding levels, does not necessarily reflect a change in the amount of money the NIH received from Congress or a change in the actual content of the NIH research portfolio. For more information, please go to: <http://report.nih.gov/rcdc/reasons/default.aspx>.
- d. Numbers may not add due to rounding of agency budget figures.

## Selected Issues

### U.S. Competitiveness

Nanotechnology is largely still in its infancy. Accordingly, measures such as revenues, market share, and global trade statistics—which are often used to assess and track U.S. competitiveness in other more mature technologies and industries—are not available for assessing the relative U.S. position internationally in nanotechnology. To date, the federal government does not collect data on nanotechnology-related revenues, trade or employment, nor is comparable international government data available. Nevertheless, many experts believe that the United States is the global leader in nanotechnology. However, some of these experts believe that in contrast to many previous emerging technologies—such as semiconductors, satellites, software, and biotechnology—the U.S. lead is narrower, and the investment level, scientific and industrial infrastructure, technical capabilities, and science and engineering workforces of other nations are more substantial than in the past.

In the absence of comprehensive and reliable economic output data (e.g., revenues, market share, trade), indicators such as inputs (e.g., public and private research investments) and non-financial outputs (e.g., scientific papers, patents) have been used to gauge a nation’s competitive position in emerging technologies. By these measures (discussed below), the United States appears to lead the world, generally, in nanotechnology. However, R&D investments, scientific papers, and patents may not provide reliable indicators of the United States’ current or future competitive position. Scientific and technological leadership may not necessarily result in commercial leadership or national competitiveness for a variety of reasons:

- Basic research in nanotechnology may not translate into viable commercial applications.
- Basic research is generally available to all competitors.
- U.S.-based companies may conduct production and other work outside of the United States.
- U.S.-educated foreign students may return home to conduct research and create new businesses.
- U.S. companies with leading-edge nanotechnology capabilities and/or intellectual property may be acquired by foreign competitors.
- U.S. policies or other factors may prohibit nanotechnology commercialization, make it unaffordable, or make it less attractive than foreign alternatives.
- Aggregate national data may be misleading as countries may establish global leadership in niche areas of nanotechnology.

With these caveats, the following section reviews input and non-economic output measures as indicators of the U.S. competitive position in nanotechnology.

## Global Funding

The United States has led, and continues to lead, all nations in known public investments in nanotechnology R&D, though the estimated U.S. share of global public investments has fallen as other nations have established similar programs and increased funding. Using a currency exchange rate comparison, the United States ranks ahead of all other nations, with federal and state investments of \$1.78 billion in 2006 (27.8% of global public R&D investments), followed by Japan (\$975 million, 15.2%) and Germany (\$563 million, 8.8%). When national investments are adjusted using purchasing power parity (PPP) exchange rates,<sup>12</sup> the United States remains the world leader, but China ranked second in public nanotechnology spending in 2005.<sup>13</sup>

Private investments in nanotechnology R&D come from two primary sources, corporations and venture capital investors. On a PPP comparison basis, the United States led the world in 2006 in corporate R&D investments in nanotechnology with an estimated \$1.9 billion investment, followed by Japan with \$1.7 billion. In total, U.S. and Japan-based companies accounted for nearly three-fourths of global corporate investment in nanotechnology R&D in 2006. China ranks fifth in corporate investment, accounting for approximately 3% of global private R&D investments.<sup>14</sup> Lux Research, an emerging technologies consulting firm, estimates that global nanotechnology venture capital investment in 2007 was \$702 million, of which \$632 million went to U.S.-based firms.<sup>15</sup>

## Scientific Papers

The quantity of peer-reviewed scientific papers is considered by some to be an indicator of a nation's scientific leadership. A study by the National Bureau of Economic Research in 2005 reported that the U.S. share was a world-leading 24%, but that this represented a decline from approximately 40% in the early 1990s, concluding:

Taken as a whole these data confirm that the strength and depth of the American science base points to the United States being the dominant player in nanotechnology for some time to come, while the United States also faces significant and increasing international competition.<sup>16</sup>

One measure of the importance of a scientific paper is the number of times it is cited in other papers. An analysis by Evaluametrics, Ltd. reports that nanotechnology papers attributed to the United States are much more frequently cited than those attributed to China, the nations of the European Union (EU27), and the rest of the world as a whole. This held true overall and separately in each of the four disciplines examined (biology, chemistry, engineering, and physics). The U.S. lead was particularly pronounced in biology. China fell below the world average number of citations in each discipline, as well as overall. The EU27 performed near the world average in engineering and physics, and somewhat higher in chemistry.

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<sup>12</sup> Purchasing power parity exchange rates seek to equalize the purchasing power of currencies in different countries for a given basket of goods and/or services.

<sup>13</sup> *Profiting from International Nanotechnology*, Lux Research, Inc., December 2006.

<sup>14</sup> *Profiting from International Nanotechnology*, Lux Research, Inc., December 2006.

<sup>15</sup> Personal communication between CRS and Lux Research, April 28, 2008.

<sup>16</sup> Zucker, L.G. and M.R. Darby. "Socio-Economic Impact of Nanoscale Science: Initial Results and Nanobank," National Bureau of Economic Research, March 2005.

## Patents

Patent counts—assessments of how many patents are issued to individuals or institutions of a particular country—are frequently used to assess technological competitiveness. By this measure, the U.S. competitive position appears to be strong. A 2007 U.S. Patent and Trademark Office analysis of patents in the United States and in other nations stated that U.S.-origin inventors and assignees/owners have:

- the most nanotechnology-related U.S. patents by a wide margin;
- the most nanotechnology-related patent publications globally, but by a narrower margin (followed closely by Japan); and
- the most nanotechnology-related inventions that have patent publications in three or more countries, 31.7%, followed by Japan (26.9%), Germany (11.3%), Korea (6.6%), and France (3.6%).<sup>17</sup>

## Environmental, Health, and Safety Implications

Key policy issues associated with U.S. competitiveness in nanotechnology include environmental, health, and safety (EHS) concerns, nanomanufacturing, and public understanding and attitudes. EHS concerns include both direct consequences for health, safety, and the environment, and how uncertainty about EHS implications and potential regulatory responses might affect U.S. competitiveness. One such effect might be the discouragement of investment in nanotechnology due to the possibility of regulations that might bar products from the market, impose high regulatory compliance costs, or result in product liability claims and clean-up costs.

Some of the unique properties of nanoscale materials—e.g., small size, high surface area-to-volume ratio—have given rise to concerns about their potential implications for health, safety, and the environment. While nanoscale particles occur naturally and as incidental by-products of other human activities (e.g., soot),<sup>18</sup> EHS concerns have been focused primarily on nanoscale materials that are intentionally engineered and produced.

Much of the public dialogue about risks associated with nanotechnology has focused on carbon nanotubes (CNTs) and other fullerenes (molecules formed entirely of carbon atoms in the form of a hollow sphere, ellipsoid, or tube) since they are currently being manufactured and are among the most promising nanomaterials. These concerns have been amplified by some research on the effects of CNTs on animals, and on animal and human cells. For example, researchers have reported that carbon nanotubes inhaled by mice can cause lung tissue damage;<sup>19</sup> that buckyballs (spherical fullerenes) caused brain damage in fish;<sup>20</sup> and that buckyballs can accumulate within

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<sup>17</sup> Eloshway, Charles. “Nanotechnology Related Issues at the U.S. Patent and Trademark Office,” Workshop on Intellectual Property Rights in Nanotechnology: Lessons from Experiences Worldwide, Brussels, Belgium, April 2007.

<sup>18</sup> Some naturally occurring nanoparticles cause adverse health effects. Studies on the effects of naturally occurring particles are numerous and inform R&D on engineered nanoparticles.

<sup>19</sup> Lam, C.; James, J.T.; McCluskey, R.; and Hunter, R. “Pulmonary toxicity of single-wall carbon nanotubes in mice 7 and 90 days after intratracheal instillation,” *Toxicological Sciences*, September 2003. Vol 77. No. 1. pp 126-134.

<sup>20</sup> Oberdörster, Eva. “Manufactured Nanomaterials (Fullerenes, C60) Induce Oxidative Stress in the Brain of Juvenile Largemouth Bass,” *Environmental Health Perspectives*, July 2004. Vol. 112. No. 10.

cells and potentially cause DNA damage.<sup>21</sup> On the other hand, some research has found CNTs and fullerenes to be non-toxic. In addition, work at Rice University's Center for Biological and Environmental Nanotechnology conducted in 2005 found cell toxicity of CNTs to be low and that toxicity can be reduced further through simple chemical changes to the CNT's surface.<sup>22</sup>

Among the potential EHS benefits of nanotechnology are applications that may reduce energy consumption, pollution, and greenhouse gas emissions; remediate environmental damage; cure, manage, or prevent deadly diseases; and offer new materials that protect against impacts, self-repair to prevent catastrophic failure, or change in ways that provide protection and medical aid to soldiers on the battlefield.

Potential EHS risks of nanoscale particles in humans and animals depend in part on their potential to accumulate, especially in vital organs such as the lungs and brain, that might harm or kill, and diffusion in the environment that might harm ecosystems. For example, several products on the market today contain nanoscale silver, an effective antibacterial agent. Some scientists have raised concerns that the dispersion of nanoscale silver in the environment could kill microbes that are vital to ecosystems.

Like nanoscale silver, other nanoscale particles might produce both positive and negative effects. For example, some nanoscale particles have the potential to penetrate the blood-brain barrier, a structure that protects the brain from harmful substances in the blood. Currently, the barrier hinders the delivery of therapeutic agents to the brain.<sup>23</sup> The characteristics of some nanoscale materials may allow pharmaceuticals to be developed to purposefully and beneficially cross the blood-brain barrier and deliver medicine directly to the brain to treat, for example, a brain tumor. Alternatively, other nanoscale particles might unintentionally pass through this barrier and harm humans and animals.

There is widespread uncertainty about the potential EHS implications of nanotechnology. A survey of business leaders in the field of nanotechnology indicated that nearly two-thirds believe that "the risks to the public, the workforce, and the environment due to exposure to nano particles are 'not known,'" and 97% believe that it is very or somewhat important for the government to address potential health effects and environmental risks that may be associated with nanotechnology.<sup>24</sup>

Many stakeholders believe that concerns about potential detrimental effects of nanoscale materials and products on health, safety, and the environment—both real and perceived—must be addressed for a variety of reasons, including:

- protecting and improving human health, safety, and the environment;
- enabling accurate and efficient risk assessments, risk management, and cost-benefit trade-offs;

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<sup>21</sup> "Understanding Potential Toxic Effects of Carbon-Based Nanomaterials," *Nanotech News*, National Cancer Institute Alliance for Nanotechnology in Cancer, July 10, 2006.

<sup>22</sup> "Modifications render carbon nanotubes nontoxic," press release, Rice University, October 2005.

<sup>23</sup> "Blood-Brain Barrier Breached by New Therapeutic Strategy," press release, National Institutes of Health, June 2007.

<sup>24</sup> "Survey of U.S. Nanotechnology Executives," Small Times Magazine and the Center for Economic and Civic Opinion at the University of Massachusetts-Lowell, Fall 2006.

- creating a predictable, stable, and efficient regulatory environment that fosters investment in nanotechnology-related innovation;
- ensuring public confidence in the safety of nanotechnology research, engineering, manufacturing, and use;
- preventing the negative consequences of a problem in one application area of nanotechnology from harming the use of nanotechnology in other applications due to public fears, political interventions, or an overly-broad regulatory response; and
- ensuring that society can enjoy the widespread economic and societal benefits that nanotechnology may offer.

Policy issues associated with EHS impacts of nanotechnology include magnitude, timing, foci, and management of the federal investment in EHS research; adequacy of the current regulatory structures to protect public health and the environment; and cooperation with other nations engaged in nanotechnology R&D to ensure all are doing so in a responsible manner.

## **Nanomanufacturing**

Securing the economic benefits and societal promise of nanotechnology requires the ability to translate knowledge of nanoscience into market-ready nanotechnology products.

Nanomanufacturing is the bridge connecting nanoscience and nanotechnology products. Although some nanotechnology products have already entered the market, these materials and devices have tended to require only incremental changes in manufacturing processes. Generally, they are produced in a laboratory environment in limited quantities with a high-degree of labor intensity, high variability, and high costs. To make their way into safe, reliable, effective, and affordable commercial-scale production in a factory environment may require the development of new and unique technologies, tools, instruments, measurement science, and standards for nanomanufacturing.

## **Public Attitudes and Understanding**

What the American people know about nanotechnology and the attitudes that they have toward it may affect the environment for research and development (especially support for public R&D funding), regulation, market acceptance of products incorporating nanotechnology, and, perhaps, the ability of nanotechnology to weather a negative event such as an accident or spill.

In 2007, the Woodrow Wilson International Center for Scholars' Project on Emerging Nanotechnologies (PEN) reported results of a nationwide poll of adults that found more than 42% had "heard nothing at all" about nanotechnology, while only 6% said they had "heard a lot." In addition, more than half of those surveyed felt they could not assess the relative value of nanotechnology's risks and benefits. Among those most likely to believe that benefits outweigh risks were those earning more than \$75,000 per year, men, people who had previously heard "some" or "a lot" about nanotechnology, and those between the ages of 35 and 64. Alternatively, among those most likely to believe that the risks of nanotechnology outweigh benefits include

people earning \$30,000 or less; those with a high school diploma or less; women; racial and ethnic minorities; and those between the ages of 18 and 34 or over age 65.<sup>25</sup>

The PEN survey found a strong positive correlation between familiarity with and awareness of nanotechnology and perceptions that benefits will outweigh risks. However, the survey data also indicate that communicating with the public about nanotechnology in the absence of clear, definitive answers to EHS questions could create a higher level of uncertainty, discomfort, and opposition.

Congress expressed its belief in the importance of public engagement in the 21<sup>st</sup> Century Nanotechnology Research and Development Act of 2003 (15 U.S.C. §§7501 et seq.). The act calls for public input and outreach to be integrated into the NNI's efforts. The NNI has sought to foster public understanding through a variety of mechanisms, including written products, speaking engagements, a web-based information portal (nano.gov), informal education, and efforts to establish dialogues with key stakeholders and the general public. In addition, the NSET subcommittee has established a Nanotechnology Public Engagement and Communications working group to develop approaches by which the NNI can communicate more effectively with the public.

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<sup>25</sup> “Awareness of and Attitudes Toward Nanotechnology and Federal Regulatory Agencies: A Report of Findings,” survey by Peter D. Hart Research Associates, Inc., for the Project on Emerging Nanotechnologies, September 2007.